REMARKS

Claims 21, 23-27 and 41-44 are pending in this application. Claims 21, 23-27 and 41-44 stand rejected.

The preambles of claims 23-27 and 41 have been amended to recite "the antibody or fragment thereof of claim 21". Claim 42 has been amended to recite "A hybridoma that is capable of producing an antibody that specifically binds a polypeptide consisting of SEQ ID NO:2."

Written support for the amendment of claim 23 appears in the present application at, *e.g.*, page 22, lines 21-29; page 25, lines 16-25; and page 54, lines 15-19. Written support for the amendment of claim 23 appears in priority application no. 60/101,318 ("the '318 provisional application") at, *e.g.*, page 24, lines 13-27; page 27, lines 18-29; and page 58, lines 30-35.

Written support for the amendment of claim 24 appears in the present application at, *e.g.*, page 7, lines 20-23 and in the '318 provisional application at, *e.g.*, page 5, lines 27-31.

Written support for the amendment of claim 25 appears in the present application at, *e.g.*, page 25, line 31 to page 26, line 1 and in the '318 provisional application at, *e.g.*, page 27, line 36 to page 28, line 1.

Written support for the amendment of claim 26 appears in the present application at, *e.g.*, page 7, lines 20-27; page 25, lines 10-15; and page 54, lines 15-19. Written support for the amendment of claim 26 appears in the '318 provisional application at, *e.g.*, page 5, lines 27-36; page 24, lines 32-34; and page 58, lines 30-35.

Written support for the amendment of claim 27 appears in the present application at, *e.g.*, page 24, lines 20-21 and in the '318 provisional application at, *e.g.*, page 26, lines 19-21.

Written support for the amendment of claim 41 appears in the present application at, *e.g.*, page 25, line 31 to page 26, line 1 and in the '318 provisional application at, *e.g.*, page 27, line 36 to page 28, line 1.

Written support for the amendment of claim 42 appears in the present application at, *e.g.*, page 54, line 20 and in the '318 provisional application at, *e.g.*, page 58, line 36.

These amendments add no new matter.

Indefiniteness Rejections under 35 U.S.C. § 112, Paragraph 2

The Examiner has rejected claims 23-27 and 41 as indefinite under 35 U.S.C. § 112, Paragraph 2. According to the Examiner, "the preamble of the instant claims lacks sufficient antecedent basis in claim 21, and therefore the instant claims are indefinite." Applicants have obviated the rejection by amending the preambles of claims 23-27 and 41 to recite "the antibody or fragment thereof of claim 21".

The Examiner also asserts that claim 42 is indefinite under 35 U.S.C. § 112, Paragraph 2 because "'***a hybridoma***' cannot ***comprise an antibody*** as a hybridoma is a cell line that produces an antibody". In keeping with the Examiner's suggestion, applicants have converted claim 42 to independent form and amended it to recite a hybridoma "that is capable of producing an antibody that specifically binds a polypeptide consisting of SEQ ID NO:2."

In view of the above amendments, withdrawal of the rejections under 35 U.S.C. § 112, Paragraph 2 is respectfully requested.

Anticipation Rejection under 35 U.S.C. § 102(e)

Claims 21, 23-27 and 41-44 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,555,520 ("the '520 patent") as evidenced by Bost *et al.*, IMMUNOL. INVEST. 17: 577-586 (1988) and Bendayan *et al.*, J. HISTOCHEM. CYTOCHEM. 43: 881-886 (1995).

Underlying the anticipation rejection is the allegation that the 09/399,492 grandparent application, the 60/131,298 provisional application, and the 60/101,318 provisional application ("the '318 provisional application") fail to disclose a utility for the claimed invention. The Examiner concludes that

> the effective filing date of the instant claims is September 25, 2001 because it was only with the filing of 09/963,347 on September 25, 2001 that a utility for the polypeptide of SEQ ID NO:2, and the antibodies that bind said sequence, was established.

Applicants respectfully disagree. Utility for the claimed invention is disclosed in the '318 provisional application. As a result, the claimed invention has the benefit of priority to the '318 provisional application, and the '520 patent is not available as prior art.

Utility for the Claimed Invention Is Disclosed in the '318 Provisional Application

The '318 provisional application states that "[i]t is likely that IL-B50 has either stimulatory or inhibitory effects on hematopoietic cells, including, e.g., lymphoid cells, such as T-cells, B-cells, natural killer (NK) cells, macrophages, dendritic cells, hematopoietic progenitors, etc." *See* '318 provisional application, p. 9, ll. 9-13. This asserted utility was based on the inventors' recognition of the significant sequence and structural similarity between IL-7 and IL-B50. *See, e.g.,* '318 provisional application, p. 4, ll. 20-22; p. 12, ll. 1-4. As discussed below, this utility is specific, substantial and credible as required by 35 U.S.C. § 101. Accordingly, the instant application is entitled to the filing date of the '318 provisional application.

In order to meet the utility requirement, the claimed invention must have a specific, substantial and credible utility. Regarding substantial utility, the MPEP states that "any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a 'substantial' utility." *See* MPEP § 2107.01. Regarding specific utility, the MPEP states that

a "statement of specific utility should fully and clearly explain why the applicant believes the invention is useful." *Id.*

The MPEP states that "[i]n most cases, an applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement." *See* MPEP § 2107.02. The MPEP clearly states that "[i]f the asserted utility is credible (*i.e.*, believable based on the record or the nature of the invention), a rejection based on 'lack of utility' is not appropriate." The MPEP cautions Examiners not to begin an evaluation of utility by assuming that an asserted utility is likely to be false, based on the technical field of the invention or for other general reasons. *Id.*

The Asserted Utility is Specific and Substantial

The '318 provisional application asserts at least one specific and substantial utility for the claimed invention. For example, the '318 provisional application states that "[i]t is likely that IL-B50 has stimulatory or inhibitory effects on hematopoeitic cells", including B cells and T cells. *See* '318 provisional application, p. 9, ll. 9-13. The asserted utility of modulating (i.e., stimulating or inhibiting) the proliferation of B cells and T cells is specific and substantial due to the involvement of these cells in immunotherapy and autoimmunity.

The fact that the specification states that the claimed polypeptides could have stimulatory or inhibitory effects on hematopoietic cells does not render the stated utility general or insubstantial. The Utility Guidelines state that "specific utility" is meant to distinguish situations where an applicant has disclosed an actual specific utility from situations where an applicant merely indicates that the invention may prove useful without identifying with specificity why the invention is considered useful. MPEP § 2107.01(I)(A). Examples of general or insubstantial utilities provided in the MPEP include the use of a compound to treat an unspecified disorder or the assertion that a compound has broadly general useful biological properties. *Id.* Clearly, the utility asserted in the '318 provisional

application – the use of the claimed polypeptides to modulate (*i.e.* stimulate or inhibit) the proliferation of hematopoietic cells – is specific and substantial, and meets the utility standards set out in the MPEP.

The Asserted Utility is Credible

The Examiner argues that the similarity between IL-B50 and IL-7 does not demonstrate that the claimed polypeptide is useful. Stating that only "a handful of residues were identical between the IL-B50 and IL-7", the Examiner asserts that one of ordinary skill in the art "would not have reasonably concluded that the IL-B50 polypeptide possesses any or all of the biological activities of IL-7." The Examiner concludes that the only use for antibodies against IL-B50 would be as an object of further research.

The credibility of the utility is judged from the "perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (*e.g.*, test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant's assertions. An applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement." *See* MPEP § 2107. The MPEP states that an assertion of utility is credible "unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion." *See* MPEP § 2107.02.

As discussed in the declaration of Dr. Andrej Sali submitted June 19, 2007 in co-pending patent application 09/963,347 (the "Sali Declaration") (a copy of which is submitted herewith), even though IL-B50 and IL-7 share only about 28% sequence homology, a person of skill in the art would have found the asserted utility to be credible. IL-7 is a member of the hematopoietin subgroup of cytokines. As of the filing date of the '318 provisional application, it was known in the art that the overall sequence homologies among individual members of the hematopoietin subgroup of cytokines are notably low. *See, e.g.,* Kroemer *et*

al., PROTEIN ENG. 9(6): 493-498 (1996) at 493, submitted in the concurrently filed Information Disclosure Statement. It was also known in the art that the hematopoietins display a common fold, described as four-helix bundles with an up-up-down-down topology. *Id.*; Sali Declaration ¶ 11. Thus, the skilled artisan would not have doubted applicants' assertion that IL-B50 and IL-7 have similar functions simply because the sequence homology between the molecules was low.

Instead, the significance of the disclosed similarity between IL-7 and IL-B50 could have been confirmed by a person of skill in the art at the time that the provisional application was filed. Sali Declaration ¶¶ 6-13. For example, the significance of the similarity could have been confirmed using computer programs available at the time the '318 provisional application was filed. Sali Declaration ¶¶ 6-10. Further, the areas of similarity between IL-7 and IL-B50 correspond to the regions in IL-7 that are important for binding other proteins, including IL-7R. *Id.* ¶ 11. A person of skill in the art would have appreciated that these "binding regions" are the ones wherein the homology between IL-7 and IL-B50 is highest. *Id.* Thus, a person of skill in the art at the time the '318 provisional application was filed would have believed applicants' statements regarding the similarity between IL-B50 and IL-7 and would have found the asserted utility to be credible.

Further, it was well known in the art by September 1998 that IL-7 stimulated the proliferation of B and T cells. *See, e.g.,* Kroemer *et al.*, PROTEIN ENG. 9(6): 493-498 (1996); Valenzona *et al.*, CYTOKINE 10(6): 404-412 (1998); Miyaji *et al.*, CELL. IMMUNOL. 169(2): 159-165 (1996); Winkler *et al.*, BLOOD 85(8): 2045-2051 (1995); all submitted in the concurrently filed Information Disclosure Statement. As noted above, the '318 provisional application teaches that IL-B50 is structurally similar to IL-7 and that it shares biological functions with IL-7. One of skill in the art at the time that the application was filed would have found that disclosure credible. Sali Declaration ¶¶ 5, 13. Moreover, post-filing-date art

confirms that IL-B50 (currently known in the art as TSLP) does indeed stimulate the proliferation of B cells and T cells, similar to IL-7. *See, e.g.*, Al-Shami *et al.*, J EXP. MED. 200(2): 159-168 (2004); Quentmeier *et al.*, LEUKEMIA 15(8): 1286-1292 (2001), submitted in the concurrently filed Information Disclosure Statement.

Applicants point out that post-filing-date scientific papers, such as the scientific articles and declaration discussed above, may be used to corroborate applicants' asserted utility. Legal precedent for the use of post-filing-date references in this manner can be found in *In re Brana*, 51 F.3d 1560, 1567 (Fed. Cir. 1995), where the Federal Circuit stated that:

> The Kluge declaration, though dated after applicants' filing date, can be used to substantiate any doubts as to the asserted utility since this pertains to the accuracy of a statement already in the specification. *In re Marzocchi*, 439 F.2d at 224 n.4, 169 U.S.P.Q. (BNA) at 370 n.4.

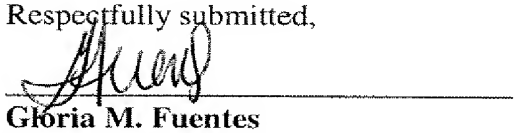
As shown by the evidence discussed above and by the concurrently submitted Sali Declaration, a specific, substantial, and credible utility for the claimed invention is disclosed in the '318 provisional application. Similarly, because the claimed invention was described as having a clear and well-established utility for the reasons set forth above, one of ordinary skill in the art clearly would have known how to use the claimed invention as of September 1998.

Because the claimed invention has the benefit of priority to the '318 provisional application, the '520 patent is not available as prior art. Applicants respectfully request that this rejection be reconsidered and withdrawn.

CONCLUSION

Based on the foregoing amendments and remarks, applicants request withdrawal of the outstanding rejections and allowance of the pending claims. If any issues remain after the Examiner has considered these remarks, applicants invite the Examiner to contact the undersigned by telephone.

Respectfully submitted,



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